

REMARKS

This responds to the Office Action mailed November 12, 2004.

Claims 1, 17, and 34 are amended, claims 4, 11, 14, and 19-32 are cancelled, and no claim is added; as a result, claims 1-3, 5-10, 12, 13, 15-18, 33 and 34 are pending in this application. Applicants note with appreciation the allowability of claims 10, 13, 16, and 33.

The current claims recite that the present pharmaceutical carrier and the layered film thereof are water-erodible. Support exists throughout the specification, e.g., at page 6, lines 6-12. No new matter has been introduced.

Personal Interview with Examiner

Applicants' wish to thank Examiner Webman for extending the courtesy of a personal interview to Applicants' representative, Richard A. Schwartz, on February 9, 2005.

Applicants' representative pointed out that the device of Takayanagi et al. must include a support layer, which is intestine-soluble and not water-erodible. In contrast, Applicants' entire device is water-erodible. The Examiner agreed to insertion of the phrase *water-erodible* into the preambles of the rejected independent claims, and that the inserted phrase would be given patentable weight.

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicants respectfully request that the Examiner point out any deficiencies in his next communication so that Applicants can amend or supplement the interview summary.

§103 Rejections of the Claims

A. First Rejection

The PTO has rejected claims 1-3, 5, 6, 9, 12, 15, 17, and 18 under 35 USC § 103(a) as being unpatentable over Takayanagi et al. in view of Ventouras. The PTO has reasserted the basis for the rejection as given in the December 23, 2003 Office action and has pointed out that in contrast to Applicants' assertions, Ventouras recites hydroxypropyl cellulose at col. 2, lines 21-23. The PTO has also stated that Ventouras is cited only for its teaching of swellable polymers. The PTO asserts that this disclosure is relevant to any composition. This rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the reference or to combine reference teachings. Second, the reference(s) must teach or suggest all the claim limitations. Finally, there must be a reasonable expectation of success. The teaching or suggestion to make the claimed modification and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143. For at least the reason that the cited documents do not teach or suggest all the claim limitations, the rejection is improper.

Applicants submit that the combination of prior art references does not teach, suggest or disclose all the elements of Applicants' claims. In particular, the combination of prior art references does not teach, suggest, or disclose a pharmaceutical carrier device that it is entirely water-erodible.

Applicants' inventive carrier device is a film of at least two layers. The first layer is a water-erodible adhesive layer and the second layer is a water-erodible non-adhesive backing layer. A pharmaceutical compound may be included in either or both layers. The entire device is water-erodible.

In contrast, the primary document cited in the rejection, Takayanagi et al., discloses a medical tape of at least two layers for use on oral mucosa. The tape includes one or more medicament layers and a support layer (col. 2 lines 7-10). The support layer is intestine-soluble and does not erode in the oral cavity; dissolution of the support layer "scarcely occurs" (col. 2,

lines 60-65). Therefore, the entire device of Takayanagi et al. is not water-erodible. The disclosure of Ventouras contains nothing to remedy the deficiency of Takayanagi et al. For this reason, Applicants respectfully submit that the combination of documents does not suggest their invention.

Without the presence of all the claim elements in the cited documents, there would have been no motivation or reasonable expectation of success to reach Applicants' invention, absent Applicants' disclosure. Withdrawal of this rejection is respectfully requested.

B. Second Rejection

The Examiner has also rejected claims 1-3, 5-9, 12, 15, 17, 18, and 34 as obvious over a combination of Takayanagi et al., Ventouras, WO95/05416 and EPA 250187. Applicants respond that the latter two documents do not correct the above-discussed deficiency of Takayanagi et al. As the Examiner states, the WO document discloses overlaying to prevent leakage and the EPA document discloses flavors. These features are not directed to the deficiency of Takayanagi et al. as discussed above.

Applicants respectfully submit that this combination also does not render their claims obvious. Applicants respectfully request withdrawal of this rejection.

Conclusion

Applicants respectfully request reconsideration of their claims in view of these remarks and withdrawal of the rejections. Applicants respectfully solicit allowance of their claims and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6939 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By their Representatives,

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Date

Feb 25, 2005

By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 25 day of February, 2005.

Name

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